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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/993,696	12/18/1997	DAVID J. SCHANZLIN	251692002821	5525

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Antoinette F. Konski
McCutchen Doyle Brown & Enersen LLP
Three Embaracadero Center, Suite 1800
San Francisco, CA 94111-4067

EXAMINER
WILLSE, DAVID H

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/993,696	Applicant(s) SCHANZLIN ET AL.	
	Examiner Dave Willse	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2002* .

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-103* is/are pending in the application.

4a) Of the above claim(s) *68-85 and 95-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The disclosure is objected to because of the following informalities: On page 19, line 23, "my" should be replaced by --may--. On page 25, line 16, "are" should be deleted. On page 36, line 16, "Preferably" is misspelled. Other errors were noted. Appropriate correction is required.

Claims 68-85 have been renumbered as claims 86-103. The previously submitted method claims 50-67 have been renumbered as claims 68-85.

Claims 68-85 and 95-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim.

Claims 86-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 86, lines 3-4, "the centroidinal axis" lacks a proper antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 86, 87, 90, and 94 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Herrick, US 4,781,187.

Claims 88, 89, and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrick, US 4,781,187. Regarding claims 88 and 89, the particular radius of curvature would have been immediately obvious from the intended use of the device, as best illustrated by Figures 3, 4, 7, and 9. Regarding claims 91-94, although Herrick specifies typical dimensions "on the order of a length of 3.5 to 4.0 millimeters" (column 3, lines 52-56), lengths as low as 2.0 millimeters would have been obvious in order to accommodate experimentation or practice on rabbits and other small animals or to minimize the length of the corneal incisions.

Claims 86, 87, 90-92, and 94 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gonchar et al., "Interlayer Refraction Tunnel Keratoplasty in Correcting Myopia and Astigmatism". Regarding claims 91-92: page 4, line 16, of the English translation.

Claims 88, 89, and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonchar et al. A radius of curvature within the range set forth in present claims 88 and 89 would have been immediately obvious from the purpose of the alloimplants (Figure 3). In regard to claim 93, an implant having a length of 2.0 mm or less would have been obvious in order to accommodate a variety of eye sizes and refractive disorders.

Claims 86, 87, 90, and 94 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Civerchia, US 5,213,720. Regarding claim 86, the embodiments shown in Figures 14 and 17 can be inserted into the cornea (Figure 4; column 6, lines 20-21; column 18, lines 9-12) and thus possess a radius of curvature along a centroidal axis of at least 5.0 mm.

Claims 88, 89, and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Civerchia, US 5,213,720. Regarding claims 88 and 89, the particular radius of curvature would have been immediately obvious from the anatomy depicted in Figure 4. Regarding claims 91-93, the length of the tabs **132** being less than or equal to 2.0 mm would have been obvious from the drawing (Figure 17) and would have been obvious in order to lessen the trauma to the cornea.

The Applicant's remarks have been reviewed. Regarding Herrick and Gonchar et al., the Applicant contends that the use of donor corneal tissue in the insert is not claimed (Paper No. 38: page 7, second to last paragraph). Claimed is an "insert comprising a physiologically compatible polymer" (claim 86, line 2); the natural cornea comprises collagen, mucopolysaccharide, and other natural organic polymers, so the examiner does not understand how the scope of claim 86 excludes donor corneal tissue. The Applicant asserts that Civerchia "does not disclose a component which extends in a meridional direction" (Paper No. 28: page 8, lines 3-6). Both of the embodiments illustrated in Figures 14 and 17 are elongated and are to be centered on the optical axis of the eye; therefore, each lens defines a longitudinal axis that extends along a meridian of the eye. It is noted that a "meridian" is "[a] curve on a surface of revolution, formed by the intersection of a plane containing the axis of revolution with the surface" (*Webster's II New Riverside University Dictionary*, 1984); in this case, the plane contains the optical axis and said lens longitudinal axis extending along the surface of the eye.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is (703) 308-2903 and who is generally available Monday through Thursday during most of each day. The supervisor, Corrine McDermott, can be reached at (703) 308-2111. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse
November 18, 2002

DAVE WILLSE
PRIMARY EXAMINER
ART UNIT 3738